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Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/
Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/
Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF AMICI CURIAE FOR THE CENTER FOR PATIENT ADVOCACY AND THE CALIFORNIA HEALTH CARE INSTITUTE IN SUPPORT OF PETITIONER/CROSS-RESPONDENT

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STATEMENT OF INTEREST OF AMICI CURIAE

Amici are the Center for Patient Advocacy (CPA) and the California Health Care Institute (CHI).[1] CPA

[1] This brief is filed with the consent of the parties. Copies of the consent letters have been filed with the Clerk.

is a private, non-profit organization founded in 1995 to represent the interests of patients nationwide in obtaining access to safe, state-of-the-art medical care. Its members include citizens concerned about the quality of patient health care in America today; physicians and other health-care providers interested in providing their patients with the safest, most effective medical care available; and pharmaceutical and bioengineering firms engaged in the development of new medical products and concerned about the inhibiting effect of excessive government regulation and state products liability laws on their efforts to provide patients with the latest medical technology.

CPA develops and supports initiatives aimed at eliminating and reducing the restrictions imposed by both government and the private sector on the development of and access to new medical products, including both drugs and devices. CPA has proposed a number of legislative and regulatory reforms aimed at ensuring that Americans have access to safe, innovative medical treatments as soon as feasible. CPA also supports tort law reform efforts aimed at reducing the inhibiting effect that excessive liability has on patients' timely access to new medical technologies and on physicians' ability to provide the latest medical innovations to their patients. CPA's officers have testified before Congress on numerous occasions on these and related matters.

CHI is a private, non-profit organization founded in 1993 to represent the interests of California's biomedical and health care technology industry. Its members include academic research institutions as well as numerous biotechnology, medical device, and pharmaceutical firms. CHI's efforts are aimed at establishing a favorable climate for scientific discovery and innovation in the emerging medical products field. CHI conducts economic and public policy research, produces industry analyses, provides educational programs, formulates policy, and advocates the implementation of that policy at both the federal and state levels. Among other things, CHI has initiated and supported efforts to reform state products

liability laws and to provide specific protections for the suppliers of the biomaterials on which literally thousands of life-saving medical devices depend.

This case concerns whether federal law preempts state common law actions that seek to hold medical device manufacturers liable for the manufacture, labeling, or design of devices cleared for marketing to the public by the United States Food and Drug Administration (FDA) under the comprehensive regulatory scheme established by the Medical Device Amendments of 1976 (MDA or the Act), 21 U.S.C. §§ 360c-360*l*. The Court's decision will have serious implications for the quality of patient care today and for the development of new, improved, and safer medical device technology in the future.

Amici's participation will provide the Court with a broader perspective on the practical consequences of subjecting medical device manufacturers to liability under the patchwork of state tort law regimes in this country for the manufacture, labeling, or design of devices reviewed by the FDA and cleared for marketing to the public at large. Amici believe that exposing manufacturers to often excessive and unpredictable liability under divergent state tort law systems will not only stifle innovation in the emerging medical device field, but actually will diminish the quality of patient care as manufacturers withdraw existing, FDA-cleared products from the marketplace.

Congress intended to prevent this very result by enacting the MDA and, in particular, by expressly prohibiting the imposition of any state law requirements with respect to medical devices that are "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1). Amici have a direct interest in ensuring that this Court gives full effect to that unambiguously expressed intent of Congress.

SUMMARY OF ARGUMENT

The divergent patchwork of state products liability laws in this country imposes a "liability tax" that is passed on to all of us in the form of increased product costs and insurance premiums. In the case of medical products, however, products liability laws exact an additional, far greater societal toll: they stunt the development of new and improved medical products and drive existing products from the marketplace. Thus, many potentially life-saving medical products are not developed by manufacturers today because of liability concerns, and existing, FDA-cleared products are pulled from the market by manufacturers facing massive liability in suits brought by users, even though in many cases there is no scientifically credible evidence that these products are harmful. The quality of patient care in this country suffers as a result.

Congress was well aware of the compelling need to promote innovation in medical device technology when it enacted the MDA, and sought to do so by promoting research and development of investigational devices and by minimizing government interference in other development efforts. More to the point, Congress expressly preempted any state requirements that are "different from, or in addition to" the requirements for medical devices established under the MDA. 21 U.S.C. § 360k(a)(1). In enacting the MDA, Congress also sought to ensure the safety and effectiveness of products entering the marketplace. Thus, Congress established a comprehensive regulatory scheme under which devices must undergo FDA scrutiny as to safety and effectiveness, manufacturers must obtain FDA clearance before marketing their devices, and manufacturers remain under continuing FDA oversight and reporting requirements if and when their products reach the market. Congress also understood, however, that by promoting innovation in medical device technology—including by relieving manufacturers of regulation under state law—it would be contributing to the development of generation after generation of safer, more effective products to the benefit of patient care.

This case presents the question whether the MDA preempts state common law claims against manufacturers of FDA-cleared devices for manufacturing, labeling, or design defects. Congressional intent is the touchstone of this Court's preemption analysis. Here, honoring that intent requires holding these state law claims preempted. There is no basis for concluding, as did the court below, that some state products liability claims—but not others—should be preempted. That would contravene Congress' intent, because it would trigger the same liability concerns and thus undermine—if not entirely defeat—Congress' efforts to foster innovation in the emerging medical device industry and thereby improve the quality of patient care. Holding state common law claims preempted will not threaten the safety or effectiveness of medical devices marketed for public use. In enacting the MDA, Congress decided to rely on comprehensive federal regulation and FDA oversight—not lay juries charged with applying state products liability laws—to ensure medical device safety and effectiveness.

That was a wise decision. It is, in any event, not for this Court to second-guess that policy judgment here. Instead, this Court should give full effect to the unambiguously expressed intent of Congress. The quality of patient care and the prospects for the development of new, improved, and safer medical devices depend on it.

ARGUMENT

I. THE MDA ESTABLISHED A COMPREHENSIVE REGULATORY SCHEME DESIGNED TO ENSURE THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES AND TO PROMOTE INNOVATION IN MEDICAL DEVICE TECHNOLOGY.

1. Medical devices have been around for centuries. King George III was placed in restraints to "treat" his affliction with what is now believed to have been a metabolic disorder. George Washington is said to have had wooden teeth. Melville's Captain Ahab moved about

with the assistance of a prosthetic—albeit wooden—leg. Thomas Edison used a cornucopia horn to listen to his phonograph. President Franklin Roosevelt, like others in his generation who were afflicted by polio, walked only with the assistance of metal leg braces and other mechanical aids.

For most of our history, advancements in medical device technology have been unforthcoming, or sporadic at best. In the past few decades, however, medical device technology has flowered along with medical science as a whole. Devices that were unthinkable a short while ago—ultrasound imaging machines, implantable heart defibrillators, artificial joints made of synthetic materials, and intraocular lenses—have become everyday treatment options. These devices have enabled Americans to live longer, healthier, and more productive lives. New and even more breathtaking advances—including artificial organs—are currently being developed and other, perhaps unimaginable breakthroughs lie on the horizon.

2. In 1976, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) with the passage of the MDA, ushering in a new era of comprehensive federal regulation of medical devices.[2] Through this Act, Congress sought to accomplish two principal objectives: first, to protect the public by ensuring that medical devices would not be marketed until they were proven to be safe and effective, *see, e.g.*, 21 U.S.C. §§ 360c(a)(1)(A)(i), 360c(a)(1)(B), 360e(d)(2); and second, to foster innovation in medical device technology and thereby promote the development of new and improved devices. *See, e.g., id.* §§ 360j(k), 360j(g)(1). These purposes complement one another as advances in medical device technology result in safer, more effective products for use in treating patients.

[2] For a review of the history of federal regulation of medical devices prior to the MDA, see Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years*, 50 Food & Drug L.J. 163, 163-167 (1995).

References to these twin objectives abound throughout the legislative history of the MDA. For example, the Senate Report accompanying the MDA states:

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee [on Labor and Public Welfare] wants to encourage their research and development. [S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976).]

The original House Report provides:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in the field. [H.R. Rep. No. 853, 94th Cong., 2d Sess. 10 (1976).]

See also id. at 12 (the MDA "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research"); *id.* at 42 ("recogniz[ing] the necessity to encourage the discovery and development of medical devices intended for human use").

Congress reaffirmed this intent when it amended the MDA in 1990:

> Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and the government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices. [S. Rep. No. 513, 101st Cong., 2d Sess. 13 (1990).[3]]

[3] Floor statements made during the debates on the MDA and 1990 amendments are to the same effect. *See, e.g.*, 121 Cong. Rec.

3. In order to achieve these objectives, Congress established a comprehensive scheme for the regulation of all "devices intended for human use." 21 U.S.C. § 360c (a)(1). The MDA authorizes the FDA to classify medical devices into three separate categories based on the degree of regulation necessary to assure "safety and effectiveness." *Id.* § 360c. This case concerns a Class III device manufactured by petitioner/cross-respondent Medtronic, Inc. (Medtronic)—the cardiac pacemaker lead.[4] Class III devices are "for use in supporting or sustaining

S1258 (daily ed. Jan. 30, 1975) (Senate Health Subcommittee) ("recogniz[ing] the necessity to encourage scientific investigation in the medical devices field"); 122 Cong. Rec. H1722, H1725 (daily ed. Mar. 9, 1976) (statements of Rep. Carter) (recognizing "the need to continue to encourage scientific investigation and to assure product innovation"); 136 Cong. Rec. S12493 (daily ed. Aug. 4, 1990) (statement of Sen. Dodd) (the MDA "is structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products"); *id.* at S15210 (daily ed. Oct. 12, 1990) (statement of Sen. Kennedy) (recognizing the need to ensure "that growth and innovation in the medical device field continue"); *id.* at S17457 (daily ed. Oct. 27, 1990) (statement of Sen. Dodd) (the MDA sought to "foster incentives to encourage innovation in a relatively youthful industry").

These concerns were expressed during hearings on these acts as well. *See, e.g., Medical Device Safety: Hearings on H.R. 3095 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 101st Cong., 2d Sess. 73-74 (1990) [hereinafter *Hearings on Medical Device Safety*] (statement of Rep. Towns) ("As we craft new legislation, we must be careful to preserve the incentives for innovation that have pushed the frontiers of health technology forward"); *Medical Devices: Hearing Before the Senate Comm. on Labor and Human Resources*, 101st Cong., 2d Sess. 3 (1990) (statement of Sen. Hatch) ("we should work to balance the need for regulation with the benefits of innovation"); *id.* at 52 (statement of Sen. Dodd) (recognizing the consumer interest in "getting the state-of-the-art, the most modern and effective medical devices on the market").

[4] The device manufactured by Medtronic is part of a pacemaker system implanted in the body to assist the heart's natural beat by transmitting small electronic pulses from the pacemaker to the heart and by returning signals from the heart to the pacemaker. *See* Pet. Br. at 2.

human life." *Id.* § 360c(a)(1)(C)(ii)(I). They "present[] a potential unreasonable risk of illness and injury." *Id.* § 360c(a)(1)(C)(ii)(II). As a result, they are subject to the most stringent federal regulation.[5]

The FDA's review of Class III devices is governed by a complex web of federal rules and regulations. Some Class III devices are required to undergo a premarket approval (PMA) process. As part of that process, manufacturers must submit detailed information to the FDA concerning, *inter alia*, intended use, design specifications, manufacturing methods, performance standards, and labeling. *Id.* § 360e(c)(1). Two categories of Class III devices were excluded from the Act's PMA requirement: devices introduced prior to May 28, 1976 (the effective date of the MDA), *id.* § 360e(b)(1)(A), and certain investigational, or "IDE" devices under clinical scrutiny for safety and effectiveness. *Id.* § 360j(g)(2)(A). While already-marketed devices are not statutorily required to undergo PMA review, the FDA may require any such device to obtain premarket approval when necessary to assure product safety or effectiveness. *See* Pet. Br. at 8-9.

If a proposed Class III device is "substantially equivalent" to an already-marketed device, including one grandfathered under the Act, it is subject to the "510(k) process." *See* 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. § 807.100. Under this process, manufacturers must demonstrate to the FDA that the device in fact meets the federal "substantial equivalen[ce]" test. 21 U.S.C. §§ 360c(f)(1)(A)(ii), 360e(a). That requires showing, *inter alia*, that the device is as "safe and effective as a legally marketed device." *Id.* § 360c(i)(1)(A); 21

[5] The first two classes under the MDA are reserved for devices that pose less risk to their users. Class I devices, such as the toothbrush, pose little or no safety threat and are subject only to certain generally applicable regulations. 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 872.6855. Class II devices, such as the powered wheelchair, pose a somewhat greater risk to their users, and therefore are subject to certain device-specific controls. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 890.3860.

C.F.R. §§ 807.87, 807.100(b).[6] As part of this showing, manufacturers are required to submit detailed information to the FDA. 21 U.S.C. § 360(k); 21 C.F.R. §§ 807.87, 807.92.[7] Upon receipt of this information, the FDA may either clear the product for marketing, block its entry, or require the submission of additional data. 21 C.F.R. § 807.100(a)(3). As in the case of any already-marketed device grandfathered under the Act, the FDA may require any device subject to the 510(k) process to undergo PMA review as well. 21 U.S.C. § 360e(b).[8]

Only devices that clear these hurdles may be marketed to the public. Every device marketed for public use must be manufactured and labeled in accordance with federal standards, *see* 21 C.F.R. Parts 801, 820, and remains under the continuing supervision and control of the FDA. After a device reaches the market, the FDA may require manufacturers to submit additional information. 21 C.F.R. § 807.87(k). In addition, manufacturers themselves remain subject to recordkeeping and reporting obligations, which, *inter alia*, require manufacturers immediately to report any serious device malfunction. 21 U.S.C. §§ 360i, 360*l*; 21 C.F.R. §§ 803.1, 803.24. At any point, the FDA may rescind its marketing approval, 56 Fed. Reg. 46,191, 46,194 (Sept. 10, 1991), bar the distribution of devices, 21 U.S.C. § 360h(e)(1)(A), or recall a device altogether. *Id.* § 360h(e)(1)(B). The FDA also may seek civil and criminal penalties against manufacturers that violate MDA requirements. *See* Pet. Br. at 7.

[6] Congress codified the FDA's long-standing interpretation of "substantial equivalence," which focused on comparing the safety and effectiveness of the proposed and previously marketed devices, under the 1990 amendments to the MDA. *See* Pet. Br. at 25-26.

[7] The required information relates to device design as well as device safety and effectiveness. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. §§ 807.87, 807.92, discussed in Pet. Br. at 22-23.

[8] The medical device involved in this case eventually reached the market via the 510(k) process, but not before the FDA had required Medtronic to submit additional data concerning device design. *See* Pet. Br. at 10-11.

4. The foregoing provisions are aimed primarily at ensuring the safety and effectiveness of medical devices that enter the marketplace. As discussed, this was only one of Congress' principal objectives in enacting the MDA. In order to advance the other—promoting innovation in medical device technology—Congress established special rules governing devices developed for investigational use and rare conditions, *see* 21 U.S.C. §§ 360j(g), 360j(m), and authorized the FDA to enter into research and development contracts. *Id.* § 360j(k). More important, for present purposes, Congress explicitly preempted all state requirements with respect to medical devices "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1).[9] As discussed next, this express preemption provision is critical to Congress' effort to promote the development of new, improved, and *safer* medical devices.

II. SUBJECTING MEDICAL DEVICE MANUFACTURERS TO LIABILITY UNDER THE PATCHWORK OF STATE TORT LAW REGIMES WOULD STIFLE INNOVATION IN MEDICAL DEVICE TECHNOLOGY AND DRIVE EXISTING, FDA-CLEARED PRODUCTS FROM THE MARKETPLACE TO THE DETRIMENT OF PATIENT CARE.

1. As noted, medical device technology currently is experiencing an unprecedented period of growth. In the past fifty years, medical device technology—together with

[9] The MDA's preemption provision provides:

> Except as provided in subsection (b) * * * no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. [21 U.S.C. § 360k(a).]

Subsection (b) permits States to apply for an exemption from subsection (a)'s express preemption provision. *Id.* § 360k(b). That exemption is not implicated in this case.

medical science as a whole—has advanced at an exponential rate. Recent breakthroughs in medical device technology have vastly improved the quality of patient care in this country and have enabled Americans to live longer, healthier, and more productive lives. These advances have not come about by accident. They are the product of scientific ingenuity, numerous incremental steps in product development, and the allocation of vast private and public resources for research and development.

The medical device industry in the United States is a highly research-intensive, competitive industry comprised of small, relatively young, start-up companies. *See Hearings on Medical Device Safety, supra*, at 73; S. Rep. No. 33, *supra*, at 18. Because of the time and expense required to bring new or improved medical devices to market, most medical device firms are—at least early on—dependent upon venture capital financing. One recent study estimated that on average $10 to $20 million is required to bring a medical device from laboratory to market. *See Reforming the FDA: Hearing Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 104th Cong., 2d Sess., 1996 WL 5508897, at 3 (Feb. 27, 1996) [hereinafter *Hearing on Reforming the FDA*] (statement of John K. Clarke, director of the National Venture Capital Association). At the same time, there are enormous entrepreneurial risks associated with bringing a new medical device to market—including securing patent protection—and, in many cases, a new device will have a market lifespan of only about two to three years. *See id.*; *infra* at 19.

In 1994 alone, venture capitalists poured almost $500 million into medical device firms across the country. 1996 WL 5508897 at 2. This "seed" capital is critical to the vitality of the medical device industry. But it is far from abundant. In fact, Price Waterhouse recently reported that many small and emerging medical device companies in this country are extremely short of funds and are experiencing serious difficulties raising additional financing. *Id.* at 4. As venture capitalists seek higher and more secure returns, funding medical device firms has become a

riskier and less attractive investment option. *Id.* Yet capital investment is critical to the development of the next generation of medical devices. *See Trends in Venture Capital Funding for the Medical Device Industry* 3 (Health Care Technology Inst. Mar. 1994).

2. Exposing medical device manufacturers to state law products liability actions for alleged manufacturing, labeling, or design defects in federally-cleared devices will jeopardize the availability of that capital and have precisely the effect that Congress sought to prevent in enacting the MDA: it will stunt research and development efforts in the medical device industry and thereby stifle the development of new, improved, and safer products. But that is not all. Subjecting medical device manufacturers to state products liability laws also will cause manufacturers of existing, FDA-cleared medical devices to pull their products from the market. The real losers in this scenario are not the medical device manufacturers, but the patients who deserve access to safe, state-of-the-art medical care and the healthcare providers who wish to secure that for them.

One of the overriding concerns of private firms and individuals in the medical products market is liability under state tort law regimes.[10] This concern stems pri-

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[10] *See, e.g., Health Care Liability Reform and Quality Assurance Act of 1995, Hearing on S. 454 Before the Senate Comm. on Labor and Human Resources*, 104th Cong., 1st Sess. 38 (1995) (statement of Thomas Scully, President and CEO of the Federation of American Health Systems); *Entrepreneurship in America: Loosening the Government Noose on Small Business, Field Hearing Before the Senate Comm. on Small Business*, 104th Cong., 1st Sess. 111 (1995) (statement of E.R. Pickard, Chairman and CEO, Sofamor Danek Group, Inc.); *Product Liability: Hearing Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space, and Technology*, 102d Cong., 2d Sess. 115 (1992) [hereinafter *Hearing on Product Liability*] (statement of Dane Miller, Ph.D., President and CEO of Biomet, Inc.); *cf. Product Liability Fairness Act: Hearings on S. 640 Before the Subcomm. on Consumer of the Senate Comm. on Commerce, Science, and Transportation*, 102d Cong., 1st Sess. 55 (1991) (statement of Michael Belletire, Office of the Governor, State of Illinois) (discuss-

marily from two well-recognized—and unsettling—features of the current products liability regimes in this country: products liability can be—and with perhaps increasing frequency is—crippling for businesses hauled into state court before juries, and yet the likelihood and extent of that liability is almost impossible to predict in a fashion that would enable businesses to regulate their conduct so as reasonably to avoid it.

Punitive damages awards "run wild" in state courts today. *Pacific Mut. Life Ins. Co.* v. *Haslip*, 499 U.S. 1, 18 (1991). *See generally* Richard Neely, *The Product Liability Mess: How Business Can Be Rescued From the Politics of State Court* (1988). These awards can permanently hobble a company in one fell swoop, and yet they are often "wholly unpredictable" and may "bear[] no necessary relation to the harm caused." *Haslip*, 499 U.S. at 12 (internal quotation marks and citation omitted). *See also TXO Production Corp.* v. *Alliance Resources Corp.*, 113 S. Ct. 2711, 2728-31 (1993) (O'Connor, J., dissenting). Moreover, in many medical products liability actions, the juries that decide businesses' fate lack the scientific expertise necessary to comprehend and resolve the complex factual issues on which liability typically hinges. *See generally* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 Tex. L. Rev. 1 (1995); Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1 (1993).

Confounding the fear and uncertainty engendered by the specter of "sky's the limit" punitive damages awards is the patchwork of state products liability regimes imposing different—and sometimes conflicting—rules on manufacturers. As one commentator has observed:

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ing companies' reluctance to produce certain pharmaceutical products because of liability concerns). *See generally The Liability Maze: The Impact of Liability Law on Safety and Innovation* (Peter W. Huber and Robert E. Litan eds. 1991) [hereinafter *Liability Maze*].

> America's diversity of *court systems* leads to a diversity of *law systems* because American judges, like their English predecessors, have extensive lawmaking powers. And because each separate court system is administratively independent, each can generate eccentric judge-made law at odds with the statutory and judge-made law of other jurisdictions. Whole fields of American law, such as contracts and torts, are creatures of court decisions rather than legislative enactments. * * * Ironically, then, although business is increasingly national in nature, most of the law that governs business is parochial state tort, contract, or property law that not only guides decisions in local state courts, but also binds local federal judges when they are called upon to decide lawsuits based on state law between citizens of different states. [Neely, *supra*, at 31.]

There are of course fifty-one different state tort law systems in this country, including the District of Columbia's. The "rules" imposed by these systems not only vary from one State to another, they differ in a critical respect from those established by federal regulatory schemes: they are imposed in a retrospective—rather than prospective—fashion.

These and related products liability concerns are real and very much on the minds of medical device manufacturers today. Indeed, one need only consider the current plight of Dow Corning Corp. For several decades, Dow Corning manufactured and marketed silicone-gel breast implants with FDA authorization. Less than one percent of Dow Corning's total revenue was derived from the sale of implant-grade silicones and silicone-gel breast implants. Today the company has been forced into Chapter 11 and is struggling to stay afloat after being hit with a "blizzard" of products liability actions by silicone-gel breast implant recipients who claim to have developed various connective-tissue disorders. The company has sought—but been

denied—the opportunity to consolidate these actions and to refer the entire matter to an independent panel of scientific experts. Numerous epidemiological, statistical, and scientific studies, moreover, have discredited plaintiffs lawyers' theories that silicone-gel breast implants are the cause of their clients' affliction. Nevertheless, breast implant litigation has forced Dow Corning and other manufacturers to the brink of elimination. *See Truth, Justice & Implants*, Wall St. J., Feb. 26, 1996, at A12; Trisha Gura, *Implant Debate to Cripple Innovation?: Liability Fears May Impede Testing, Limit Supplies*, Chi. Trib., Mar. 13, 1995, at C1; David S. Hilzenrath *et al., Surviving the Breast Implant Siege*, Wash. Post, June 24, 1994, at F1.[11]

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[11] The FDA impaneled two blue-ribbon advisory panels to examine whether silicone-gel breast implants are unsafe. Neither panel found any causal link between these implants and serious illness. In response to public concerns sparked largely by the mushrooming breast implant litigation, however, the FDA issued a "temporary" moratorium in 1992 on the use of silicone-gel breast implants except for major reconstructive surgery in limited circumstances. Since then, numerous epidemiological studies have refuted plaintiffs lawyers' claims that silicone-gel breast implants are unsafe. The latest study—the largest to date—was conducted by researchers at the Harvard Medical School and was based on data collected from 395,543 women health professionals. The study ruled out the possibility that silicone-gel breast implants pose "large risks of connective-tissue diseases," and found that any added risk posed by these implants is so small that "it will be difficult to distinguish reliably between a small hazard and no hazard" at all. Charles H. Hennekens *et al., Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*, 275 J. Am. Med. Ass'n 616, 621 (1996). This study supports the results of earlier studies—including a 1995 Harvard Medical School study and a 1994 Mayo Clinic study—finding no association between silicone-gel breast implants and connective-tissue diseases. *See id.* at 620 (discussing Jorge Sanchez-Guerrero *et al., Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995); Sherine E. Gabriel *et al., Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 New Eng. J. Med. 1697 (1994)). Nevertheless, despite the overwhelming—and growing—scientific evidence that silicone-gel breast implants are safe, these implants have been withdrawn from the marketplace because of liability concerns and no longer are available medical options for millions of American women and their physicians.

3. Fear of excessive and unpredictable state products liability causes many private firms simply to choose to stay out of the medical device industry altogether. Equally harmful from the standpoint of the long-term prospects of the medical device industry, such liability discourages already skittish venture capitalists from investing in medical device manufacturing companies. In an industry in which it can take several years—and several million dollars—to develop a product that must still pass an elaborate FDA review process before it may be marketed, liability concerns can—and with increasing frequency do—tip the balance in favor of putting one's capital investment into more conventional industries. As a result, many potentially life-saving products have not been developed—and today are not being developed—to the detriment of patient care.

As the American Medical Association (AMA) reported in one recent study.

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks. [AMA, *Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (June 1988)].[12]

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[12] Numerous commentators have recognized this growing problem as well. *See, e.g.*, Susan Bartlett Foote, *Managing the Medical Arms Race: Public Policy and Medical Device Innovation*. 149 (1992); *Liability Maze, supra*, at 334-356; Richard J. Mahoney, *Product*

It is of course difficult to quantify the stifling effect of liability concerns on the development of new medical products because it is impossible to say what is *not* being invented in medical laboratories across the country today. Nevertheless, it has been reported, for example, that liability concerns have had an inhibiting effect on the development of a vaccine for the AIDS virus. *See* Martin J. Hatlie *et al.*, *Health Care Liability: Reform in a Changing Environment*, in *State Civil Justice Reform* 47 (Roger Clegg ed. 1994); *Hearing on Product Liability*, *supra*, at 10 (statement of Rep. Rowland).[13] Liability concerns also reportedly have stunted the development of certain birth control products. *See* W. Kip Viscusi, *Reforming Products Liability* 66 (1991); Malcolm Gladwell, *U.S. Firms Abandoning Birth Control Industry in Wake of Lawsuits*, Wash. Post, May 1, 1988, at H1, col. 1.

Liability and Punitive Damages Laws Stifle Creativity and Innovation, Introduction to Jacqueline R. Denning, *et al.*, *Pernicious Ideas and Costly Consequences: The Intellectual Roots of the Tort Crisis* ix-x (Nat'l Legal Center for the Pub. Interest 1990); and authorities discussed *infra* at 18-19. *See also* U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522, at 170 (Feb. 1993) ("Evidence drawn from the experiences of particular products or from interviews with industry executives indicates liability may inhibit or preclude R&D or marketing of reproductive-related vaccines and products").

[13] Fear of excessive liability in developing and marketing an AIDS vaccine is particularly well-founded in light of the tradition of products liability suits that have been brought—and that are brought each year—against manufacturers of life-saving vaccines. *See* Peter W. Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 Colum. L. Rev. 277, 286-288 & n.49 (1985) (discussing suits brought against manufacturers of polio, swine flu, and whooping cough vaccines); *Liability Maze*, *supra*, at 341-345 (discussing suits brought against manufacturers of smallpox, measles, rubella, mumps, influenza, diphtheria, tetanus, hepatitis, meningococcal disease, and pneumococcal infection vaccines). Tragically, each year several children die from complications associated with receiving these vaccines. For all practical purposes, these deaths could be prevented only by pulling these FDA-cleared vaccines from the market. But of course millions of children are also inoculated each year from these historically crippling diseases without incident. Because of liability concerns, many manufacturers have pulled their vaccines from the market. In some cases, the cost of those vaccines that have remained on the market has increased a "hundredfold." *Brown* v. *Superior Court*, 751 P.2d 470, 479 (Cal. 1988).

Liability concerns not only inhibit major breakthroughs in medical science, they also prolong the equally important process by which incremental developments in medical products are made. In the medical device industry in particular, the development of new products can be an "evolutionary" rather than a "revolutionary" process. As one industry official put it:

> Progress usually comes through one small modification at a time. A doctor may use a device and realize that a minor modification will make it work better. He makes a suggestion, and a manufacturer develops a slightly different device. Later, the doctor realizes with another minor change, the device could be helpful for a slightly different indication or even a new procedure. And so it goes. The average lifespan of a medical device is very short (2 or 3 years). If one looks back ten years in the field of medicine and compares the devices of 1986 to current technology, he would conclude that we have made gigantic strides. And we have, but it is important to understand that, in most instances, these strides were made incrementally. One generation of devices replaced by another, and another. [*Hearing on Reforming the FDA*, *supra*, 1996 WL 5508917 at 3 (statement of Stephen L. Ferguson, COO of the Cook Group, Inc., the largest privately held medical device manufacturer in the world).]

As research and development efforts diminish, incremental improvements in product safety and effectiveness will become fewer and far between. Moreover, in the face of mounting liability concerns—and in the absence of any federal shield against state common law actions—manufacturers will become more reluctant to develop and market new and improved products. The quality of patient care will, as a result, suffer.

4. In addition to arresting the development of safer, more effective medical products, liability concerns also drive existing, FDA-cleared products from the marketplace. This can occur without any scientifically credible proof that the particular products are unsafe or ineffective. Moreover, in many cases, it is not only the product —but the manufacturer with it—that is driven from the market. In this fashion, subjecting medical device manufacturers to often excessive and unpredictable products liability under state law will not only forestall progress in the quality of patient care, but will actually cause the quality of patient care to regress as more and more products are withdrawn from the market.

The classic example involves the drug Bendectin. Bendectin is the only prescription drug cleared by the FDA for the treatment of nausea experienced by many women during pregnancy. It was successfully marketed worldwide by the Merrell Dow Company beginning in 1956, and has benefited almost two million women in the United States alone. Over time, several major products liability suits were filed against Merrell Dow (and other manufacturers of the drug) by women whose children were born with congenital defects. It has never been scientifically proven that Bendectin causes such defects. Moreover, the FDA continues to authorize the use of Bendectin by pregnant women today.[14] Nevertheless,

[14] As Judge Kozinski put it in his opinion on remand in the *Daubert* case:

> The FDA—an agency not known for its promiscuity in approving drugs—continues to approve Bendectin for use by pregnant women because 'available data do not demonstrate an association between birth defects and Bendectin.' *U.S. Dep't of Health and Human Services News*, No. P80-45 (Oct. 7, 1980). Every published study here and abroad—and there have been many—concludes that Bendectin is not a teratogen. In fact, apart from the small but determined group of scientists testifying on behalf of the Bendectin plaintiffs in this and many other cases, there doesn't appear to be a single scientist who has concluded that Bendectin causes limb reduction defects. [*Daubert* v. *Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1314 (9th Cir.) (citation omitted), *cert. denied*, 116 S. Ct. 189 (1995).]

Merrell Dow and other manufacturers have been forced to withdraw the drug from the market because of liability concerns. *See Liability Maze, supra,* at 337-341; Sanders, *supra*, at 1.

The same scenario is unfolding today in the case of silicone-gel breast implants. *See supra* at 15-16. But, in the medical device industry, this phenomenon has taken on a new, even more alarming dimension: *suppliers* of the materials necessary to make literally thousands of life-saving medical devices—*e.g.*, silicone, teflon, polyester, and polyurethane—are withdrawing from the medical device market for fear of being dragged into products liability actions brought against the manufacturers of medical devices in which their materials are used. *See Hearing on Reforming the FDA, supra,* 1996 WL 5508917 at 3 (statement of Stephen L. Ferguson); Frederick D. Baker, *Effects of Products Liability on Bulk Suppliers of Biomaterials*, 50 Food & Drug L.J. 455 (1995) [hereinafter *Bulk Suppliers*]. In terms of cost-benefit analysis, the risk of potential liability under state products liability laws—however slight in the case of a bulk supplier—far outweighs the relatively insignificant pecuniary benefits of remaining in this discrete market.[15]

For example, polyurethane is used to make pacemakers. Each year Dow Chemical (Dow) sells massive amounts of polyurethane to American industry at large, including —unwittingly, in some cases—to medical device manufacturers. Dow's sales of this compound to pacemaker

[15] Courts generally do not impose products liability on bulk suppliers of materials that are used in medical devices, provided that (1) the material has many industrial uses (beyond the medical device field), (2) the supplier has no specialized knowledge of how a particular buyer intends to use the product, and (3) the buyer substantially alters the material to create a new product. *See Bulk Suppliers, supra,* at 455. Nevertheless, when a supplier is aware that its materials are being used in medical devices, it may be subjected to liability under state products liability laws. *See id.* at 456-458 (chronicling recent cases in which suppliers of silicone, polyethylene, and teflon used in medical devices have been exposed to liability under state law).

manufacturers represent less than one-half of one percent of its total annual sales. Revenues from these sales do not begin to cover even the costs of *defending* against lawsuits brought against pacemaker manufacturers in which it is joined as a co-defendant. As a result, Dow has cut its polyurethane sales to medical device manufacturers. Again, in economic terms, the decision for companies facing such liability is straightforward. The result, however, is devastating for patients requiring FDA-cleared medical devices that depend on such materials. *See* Barnaby J. Feder, *Implant Industry Is Facing Cutback by Top Suppliers: Giants Like Du Pont and Dow Fear They'll Be Drawn into Product Liability Suits*, N.Y. Times, Apr. 24, 1994, at A1.[16]

5. For these principal reasons, it is clear that subjecting medical device manufacturers to state products liability laws for marketing federally-cleared devices would

[16] The same thing is happening today with respect to silicone. In addition to breast implants, silicone is used in manufacturing implantable catheters, pacemaker leads, and artificial fingers and toes. It also has been used to make implantable "shunts" that have been used with tremendous success in preventing brain damage and death in children born with hydrocephalus. Yet the sale of silicone to medical device manufacturers represents only a tiny fraction of major silicone producers' total sales. And, as a result of the liability crisis caused by the breast implant litigation, many silicone manufacturers are withdrawing their product from the medical device and supply market altogether. *See Implant Debate to Cripple Innovation?: Liability Fears May Impede Testing, Limit Supplies, supra*, at C1. *See also* Carol Gentry, *Lifesavers Casualty of Silicone Debate*, St. Petersburg Times, Jan. 31, 1995, at 1A (noting that Du Pont recently notified medical device manufacturers that it would no longer sell to them critical synthetic materials used in making artificial blood vessels and heart valves).

Since much of the recent flowering of medical device innovation is based on the availability of new biomaterials, this development is particularly troubling. Indeed, Congress itself has taken note of this problem and has proposed legislation to ensure the availability of critical biomaterials such as silicone. *See Bulk Suppliers, supra*, at 459 (discussing the proposed Biomaterials Access Assurance Act of 1995).

defeat the MDA's statutory aims of promoting innovation in medical device technology and thereby fostering the development of new, improved, and safer medical devices to enhance the quality of patient care. There is no need for this Court to stretch the language or import of the MDA to ensure that state products liability laws do not have this debilitating effect on the MDA's regulatory scheme. Congress itself ensured that this would not occur by expressly preempting any state requirement with respect to medical devices that is "different from, or in addition to" the requirements established under the MDA. 21 U.S.C. § 360k(a)(1). As discussed next, under this Court's precedents, that express preemption provision must be given its natural—and intended—effect.

III. TO GIVE FULL EFFECT TO THE REGULATORY SCHEME ESTABLISHED BY THE MDA, THIS COURT SHOULD HOLD THAT STATE COMMON LAW CLAIMS BROUGHT AGAINST MANUFACTURERS OF FDA-CLEARED MEDICAL DEVICES ARE PREEMPTED.

1. The touchstone of this Court's preemption analysis is congressional intent. *See New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). Congress' intent to preempt state law may be explicitly stated in a statute's text or implied from either the structure and purpose of an act or the fact that compliance with both federal and state law would be impossible. *See English* v. *General Elec. Co.*, 496 U.S. 72, 78-79 (1990). In order to give effect to Congress' intent in enacting the MDA and its 1990 amendments—to ensure the safety and effectiveness of medical devices and at the same time to promote innovation in medical device technology—this Court should hold that state common law claims for alleged manufacturing, labeling, or design defects in FDA-cleared devices are preempted.

2. To reach this conclusion, this Court need go no further than the MDA's express preemption provision. As

noted, that provision bars States from imposing with respect to medical devices "*any* requirement * * * which is different from, or in addition to, any requirement" established under the MDA. 21 U.S.C. § 360k(a) (emphasis added). *See supra* note 9. Congress intended Section 360k as a "general prohibition on non-Federal regulation" of medical devices, H.R. Rep. No. 853, *supra*, at 42, which, as discussed, was perfectly consistent with its efforts under the MDA to foster innovation in medical device technology. Under any plain reading, Section 360k requires preemption of state common law claims for alleged device manufacturing, labeling, or design defects.

Common law liability rules, just like positive enactments, impose requirements on medical device manufacturers. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 515-516 (1992) (plurality). That much is manifest from this case alone. If successful, respondents/cross-petitioners' negligent design claim would subject Medtronic to a state law *duty* to redesign its pacemaker lead. *Cf. International Paper Co.* v. *Ouellette*, 479 U.S. 481, 495 (1987). Under the theory of respondents/cross-petitioners' case, that "requirement" is necessary to ensure the safety and effectiveness of the device at issue. But this requirement is "different from" and "in addition to" the requirements contained in the federal regulatory scheme.

As Judge Posner explained in a similar context:

> The theory underlying the complaint is that the design of the [device] was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that the [device] could be sold subject * * * to [certain] requirements * * *. The plaintiff wishes in the name of state tort law to impose additional requirements—namely that the [device] have had a design that it lacked—and this engrafting of additional requirements relating to

> safety and effectiveness is forbidden by the preemption provision in the [MDA]. [*Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).]

As detailed in petitioner's brief, subjecting Medtronic and other medical device manufacturers to state common law liability rules would conflict with numerous safety and effectiveness requirements established by the MDA and accompanying regulations. This includes those requirements established by the 510(k) process pursuant to which Medtronic obtained FDA authorization to market its pacemaker lead. *See* Pet. Br. at 18-36, 44-46. As discussed, that process is, like the PMA process, aimed at ensuring device safety and effectiveness. *See supra* at 9-10 & n.6. Moreover, once a device is cleared for marketing, a manufacturer is "for all intents and purposes * * * required to continue to design, manufacture, and label the device as proposed in its original 510(k) Notification." *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400 (4th Cir.), *petition for cert. filed*, No. 95-1010 (Dec. 22, 1995). Permitting respondents/cross-petitioners to recover on any component of their state law action would flout those federal requirements and impose on Medtronic a duty to alter its manufacturing process, label, or device design that is wholly absent from the current federal regulatory scheme.

There is no basis for concluding, as did the court below, that Congress intended to insulate medical device manufacturers from some types of state products liability claims —*i.e.*, those predicated on alleged manufacturing or labeling defects—but not others—*i.e.*, those based on alleged design defects. As discussed, there are specific federal safety and effectiveness requirements governing device manufacturing, labeling, *and* design. *See supra* at 9-10. Moreover, permitting some common law tort claims to proceed against medical device manufacturers but not others would be flatly inconsistent with Congress' intent to encourage innovation in medical device technology,

because it would trigger the same liability concerns discussed above. *Cf. English* v. *General Elec. Co.*, 496 U.S. at 86 (it "would be odd, if not irrational" to conclude that Congress intended to preempt one set of state law tort claims under the Energy Reorganization Act but not others).

Congress intended for Section 360k to be given its natural effect. As discussed in the preceding section, it had important reasons for doing so. But even so, Congress did not categorically rule out the imposition of new or different state requirements in all instances. To the contrary, Congress established a specific mechanism by which States could obtain an exemption from the MDA's express preemption provision in order to impose "more stringent" requirements on medical device manufacturers necessitated by "compelling local conditions." 21 U.S.C. § 360k(b).[17] That Congress legislated this narrow exemption to Section 360k's express preemption provision provides all the more reason for this Court not to imply an additional—wholly unsupported—exemption for state products liability claims. *See Leatherman* v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 113 S. Ct. 1160, 1163 (1993) ("[*e*]*xpressio unius est exclusio alterius*").

3. Giving effect to Congress' intent to preempt state common law actions under the MDA will not open the door to increased calls for preemption under other federal statutes. Federal preemption is singularly appropriate in this case: there is an express preemption provision requiring displacement of any state requirements "different from, or in addition to" the requirements established under the federal scheme; in enacting that federal scheme, Congress clearly and repeatedly expressed its intent to advance certain statutory aims; and permitting state common law

[17] Since 1976, the FDA has granted fifteen States and the District of Columbia permission to impose additional requirements on medical device manufacturers under this provision. *See* Pet. Br. at 5 n.3.

actions to proceed in the face of this congressional intent would significantly undermine—if not entirely defeat—those statutory aims.

Nor will honoring Congress' intent threaten the safety or effectiveness of medical devices marketed for public use. As discussed below, in enacting the MDA Congress established a detailed regulatory scheme by which medical devices may enter the marketplace. There are several different routes a device may take, but all roads pass through the FDA and no Class III device may be marketed without prior FDA authorization. The level of FDA scrutiny and expertise is unmatched at the state—as well as international—level. Moreover, if and when a device reaches the marketplace, the manufacturer remains under continuing federal oversight and reporting requirements. At the same time, the FDA possesses broad authority to protect and ensure device safety and effectiveness if any problems arise. *See supra* at 9-10.

To be sure, medical devices—like all man-made devices—malfunction. No federal regulatory or state tort law regime can prevent that. But in enacting the MDA, Congress made a calculated decision to rely on federal regulation and FDA oversight and expertise—not lay juries charged with applying state products liability laws—to protect and promote medical device safety and effectiveness. Congress did so, moreover, in order to ensure that it did not stifle innovation in medical device technology and thus inhibit the development of new, improved, and safer devices to the detriment of patient care. Experience teaches that this was a wise decision. In any event, it is not for this Court to upset the balance that Congress has struck.

CONCLUSION

For the foregoing reasons, and for those set forth in petitioner Medtronic's brief, the judgment below should be reversed insofar as it permits plaintiffs to maintain state common law claims against medical device manufacturers for alleged defects in FDA-cleared devices.

Respectfully submitted,

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